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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,230	08/14/2001	Stanley B. Prusiner	06510056US4	6626

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EXAMINER

FALK, ANNE MARIE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No. 09/856,230	Applicant(s) PRUSINER, STANLEY B.	
	Examiner Anne-Marie Falk, Ph.D.	Art Unit 1632	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 03 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 9,10 and 33.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1,3-8,18,19,29,31 and 32.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11/24/04.
10. ☐ Other: \_\_\_\_\_

*Anne-Marie Falk*  
Anne-Marie Falk, Ph.D.  
Primary Examiner  
Art Unit: 1632

**Continuation of 2. NOTE:**

The proposed amendment raises new issues that would require further search and consideration. Claim 1 has been amended so that a number of limitations have been removed from the claim (i.e., known strain, known number of infectious units, known concentration), thereby broadening the scope of the claim with respect to those parameters. However, the claim continues to use the term "standardized" in the preamble, which now conflicts with the body of the claim, which does not require any particular standardization process nor any particular composition characteristics that would render the composition especially useful as a reference material or standard as defined in the specification at paragraph [0031]. Thus, if entered, the amended claims would require a new ground of rejection under 35 U.S.C. 112, second paragraph. Furthermore, the broadened scope of the claims would require further search and consideration.

Additionally, Claim 10 which depends from Claim 1 recites that the preparation of Claim 1 is produced in a transgenic mouse which is Tg(MHu2M)/Prnp<sup>0/0</sup>. The MHu2M gene is a chimeric gene encoding a chimeric prion that does not fall within the scope of Claim 1. While the term "Tg(HuPrP)/Prnp<sup>0/0</sup>" covers a wide variety of transgenes encoding human prion proteins, including polymorphic variants and pathogenic mutant forms of human prion proteins, it does not cover an artificial chimeric prion protein that is a combination of mouse and human prion sequences. Thus, if entered, the claim amendments would require a new ground of rejection under 35 U.S.C. 112, second paragraph, to address the conflicting claim language.

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**Continuation of 5.** The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

At page 6 of the response, Applicants question why Claim 32 has not been indicated as allowable. Claim 32 stands rejected under 35 U.S.C. 112, second paragraph, and therefore is not allowable. The rejection has not been addressed.

Applicants arguments have been fully considered but are moot because the arguments are directed to the claims as amended, but the amendments have not been entered for the reasons noted above.

Therefore, all standing grounds of rejection are maintained for reasons of record.